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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,121	03/24/2004	Joseph S.M. Peiris	V9661.0069	2460
DICKSTEIN SHAPIRO LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE)			EXAMINER	
			HUMPHREY, LOUISE WANG ZHIYING	
NEW YORK,	YORK, NY 10036-2714		ART UNIT	PAPER NUMBER
			1648	
			MAIL DATE	DELIVERY MODE
			08/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

· · · · · · · · · · · · · · · · · · ·	Application No.	Applicant(s)					
·	10/808,121	PEIRIS ET AL.					
Office Action Summary	Examiner	· Art Unit					
	Louise Humphrey, Ph.D.	1648					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS,							
WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period  Failure to reply within the set or extended period for reply will, by statute that the period patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION IN THE PROPERTY AND A TEMPORAL TO THE PROPERTY AND A TEMPORAL THE PROPERTY AND A TEMPORAT THE PROPERTY AND A TEMPORA	ATION.  lly be timely filed  HS from the mailing date of this communication.  NDONED (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on <u>04 April 2007</u> .							
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	,						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims	•						
4)⊠ Claim(s) <u>17,27,30,101,125,146 and 174-177</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5)⊠ Claim(s) <u>17,27,30,146,174 and 177</u> is/are allow <del>ed.</del> αЫe.							
	6)⊠ Claim(s) <u>101,125,175 and 176</u> is/are rejected.						
	7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examine	er.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)☐ The oath or declaration is objected to by the E	xaminer. Note the attached	Office Action or form PTO-152					
Priority under 35 U.S.C. § 119	•						
. 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list	t of the certified copies not re	eceived.					
Attachment(s)							
1) Notice of References Cited (PTO-892)	4) Interview Su	mmary (PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date							
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application 6) Other:							

## **DETAILED ACTION**

This Office Action is in response to the amendment filed on 04 April 2007.

Claims 17, 27, 30, 101, 125, 146 and 174-177 are pending.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 101 and 125 under 35 U.S.C. §112, second paragraph, as being indefinite is <u>maintained</u>. The recitation "a complement thereof" is indefinite with respect to the length of the sequence. The recitation "immunogenic" is not technically applicable for describing a nucleic acid. This rejection can be obviated by the following claim amendment:

101. A pharmaceutical formulation comprising a nucleic acid molecule comprising at least 8,000 contiguous nucleotides of the sequence of SEQ ID NO:15, or the full-length complement thereof, and a pharmaceutically acceptable carrier.

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The rejection of claims 115, 135 and 165 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement is <u>withdrawn</u> in response to Applicants' claim cancellation.

The rejection of claims 175-177 under 35 U.S.C. § 112, first paragraph, as failing to comply with the bio-deposit requirement is withdrawn in response to Applicants' submission of the certificate of deposit under Budapest Treaty.

## Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 175 and 176 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Claims 175 and 176, as written, do not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page 18 of specification. See MPEP 2105.

This rejection can be obviated by the following claim amendment:

175. An isolated host cell comprising the isolated nucleic acid molecule of claim 17 or 146.

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## Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D. Primary Examiner 10 August 2007 Louise Humphrey, Ph.D. Assistant Examiner

BRUCE R. CAMPELL, PH.D SUPERVISORY PATENT EXAMINER, TECHNOLOGY CENTER 1600